

### REMARKS

Claims 1-32 are pending in the application. Claims 1-20 have been rejected. Claims 21-32 are new. No claims have been allowed.

### **SPECIFICATION AMENDMENT**

Applicants have amended the specification as indicated above to correct an obvious typographical error in which "lancing aid" was used instead of "lancet system." Applicants submit that no new matter has been added.

### **PRIORITY CLAIM**

The Examiner failed to acknowledge the propriety of Applicants' priority claim to DE 10312357.1, stating that the instant application was filed more than twelve (12) months after the filing date of the priority application. Responsive thereto, Applicants respectfully suggest that the Examiner has overlooked the fact that the one year deadline to file the instant application and claim priority under 35 U.S.C. § 119, namely, March 20, 2004, fell on a Saturday. As such, the Monday, March 22, 2004 date of U.S. Express Mailing of the instant application is considered timely. 37 C.F.R. § 1.7 ("When . . . the last day fixed by statute . . . falls on Saturday, Sunday, or a Federal holiday, the action may be taken on the next succeeding business day . . ."). The Examiner is respectfully requested to acknowledge Applicants' priority claim as proper.

### **CLAIM REJECTIONS 35 U.S.C. § 102**

#### *a. Claims 1, 2, 5 and 8*

Claims 1, 2, 5, and 8 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,168,606 to Levin et al. ("Levin"). Levin discloses a single use lancing device having a lancet which cannot be removed after use. In particular, turning to Levin at column 4, line 64 - column 5, line 3, and Fig. 12, the housing includes stops 33 and 34 that prevent removal of the lancet carrier from the housing. By contrast, Applicants' amended claim 1 recites a multi-use lancing aid having a housing for inserting a removable lancet system.

"For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 677 (Fed. Cir. 1988). Since Levin does not identically disclose at least the multi-use lancing aid and the removable lancet system claimed by

Applicants, it cannot anticipate Applicants' claim 1. Further, since claims 2, 5, and 8 include all of the limitations of claim 1, they also cannot be anticipated by Levin. Applicants therefore request that the Examiner withdraw this rejection.

Applicants have otherwise amended claims 1 and 2 for clarity. "Lancing aid" was replaced with "lancet system" in line 16 of claim 1, as this was an obvious typographical error. Further, the recitation that the "[lancet] system is reinserted into the housing" has been replaced with the recitation that "reuse of the lancet system with the lancing aid after the lancet system is removed from the housing is thereby prevented." Amended claim 1 thus covers embodiments in which the lancet system can be reinserted into the housing and embodiments in which it cannot. Claim 2 covers an embodiment in which the lancet system cannot be reinserted into the housing after removal. Although the term "ejection" can be used to refer to removing the lancet system from the lancing aid, Applicants have replaced the claim term "ejection" with "removal" for clarity. The terms are used interchangeably in Applicants' specification. As discussed in more detail below, it appears that in some instances the Examiner has read the term "ejection" on a needle tip that emerges from a lancing aid during lancing. This reading was not intended by Applicants.

*b. Claims 12, 13, 14, 16, 17 and 20*

Claims 12, 13, 14, 16, 17, and 20 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,152,775 to Ruppert ("Ruppert"). Responsive thereto, and without acquiescing that this rejection has merit, Applicants have amended claim 12 to recite that "the protective portion of the needle body [is] positioned in the first position when the lancet system is removed from the lancing aid." The first position is recited in claim 12 as one in which "the protective portion of the needle body partially surrounds the needle tip." Thus, the needle tips of lancet systems embodying this claim are protected by the protective cover upon removal from the lancing aids, thereby reducing the chance of a needle stick injury from an exposed needle.

In stark contrast, Ruppert discloses a lancing device which merely pulls the protective cover from the lancet needle prior to lancing, leaving the needle tip exposed when the lancet is removed from the lancing device. Ruppert, col. 3, lines 10-15 and col. 5, lines 24-28. In this respect, Ruppert suffers from the same disadvantage Applicants acknowledged in their specification with regard to EP 0630609. Applicants' Specification, ¶ [0011]. Ruppert thus does not disclose a lancet system in which a protective portion of the needle body is in a second position in which the protective portion at least partially surrounds the needle tip when the lancet system is removed from the lancing aid, as claimed by Applicants.

Therefore, Ruppert cannot anticipate Applicants' claim 12. Diversitech, 850 F.2d at 677 ("For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference.") Further, since claims 13, 14, 16, 17, and 20 all depend from claim 12 and include the same limitations thereof, they also cannot be anticipated by Ruppert. Applicants request that the Examiner withdraw this rejection.

### **CLAIM REJECTIONS 35 U.S.C. § 103**

#### *a. Claims 3, 4 and 6*

Claims 3, 4, and 6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Levin in view of U.S. Patent No. 5,314,442 to Morita ("Morita"). Responsive thereto, Applicants submit that the combination of Levin and Morita fails to address the deficiencies of Levin discussed above with reference to base claim 1. Namely, Applicants' claim 1 calls for a housing for inserting a removable lancet system, and the lancet of the single-use device of Levin cannot be removed.

Nor does Morita disclose a housing for inserting a removable lancet system, as claimed by Applicants. Morita instead takes a different approach, teaching an end cap 121 that is threaded onto a "pricking device" 131 after the protective portion 103 is removed from the lancet body 102. Morita, col. 13, lines 10-15; Figs 4 to 8. This results in the lancet body being positioned within the end cap, where it remains. That is, after lancing, the lancet body 102 remains in the cap 121 and the entire cap with the lancet body is detached from the lancet and discarded. Morita, col. 14, lines 5-9.

Thus, neither Levin nor Morita teach or suggest a housing for inserting a removable lancet system, as claimed by Applicants. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references). Further, both of these references teach away from Applicants' claimed invention. Levin's teaching of a single use lancing device whose lancet cannot be removed from the housing is essentially the opposite of Applicants' removable lancet system. Similarly, Morita teaches a device in which the lancet is not removable from the end cap after the lancing operation. See Ormco Corp. v. Align Technology, Inc., 463 F.3d 1299, 1308 (Fed. Cir. 2006) (reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the applicant).

Aside from the deficiencies with regard to the base claim just discussed, there are additional reasons these dependent claims are non-obvious over the combination of Levin and

Morita. With regard to claim 3, assuming for the sake of argument that members 107, 122, and 113 disclosed by Morita qualified as “holding elements” as claimed, which Applicants submit is not the case, there would be no incentive or motivation for a skilled artisan to make this combination. This is because members 107, 122, and 133 disclosed by Morita have functionality that is unnecessary in a single use device such as that taught by Levin. See National Steel Car, Ltd. v. Canadian Pacific Railway, Ltd., 357 F.3d 1319, 1337 (Fed. Cir. 2004) (even if all limitations could be found in the prior art references, claimed invention not obvious without a demonstration of the motivation to combine the references).

For example, the purpose of element 107 of Morita is to retain the lancet body in the end cap 121 when the end cap is pulled from the pricking device 131. Morita, col. 13, lines 57-60. Since Levin does not contemplate a removable end cap, there would be no purpose and thus no motivation to add element 107 to the Levin device. Similarly, the purpose of the locking means 122 of Morita is to retain the lancet body 103 within the end cap 121 after the latter is removed from the pricking device 131. Again, however, Levin does not contemplate a removable end cap that contains a used lancet, but instead teaches that the entire lancing aid is discarded after a single use. There would thus be no motivation for the skilled artisan to add means 122 to Levin, whose purpose is to prevent the lancet from falling out of the cap once removed. Thus, even if the combination of Levin and Morita overcame the deficiencies noted above with regard to claim 1, which it does not, there would be no incentive to combine these references as suggested by the Examiner.

Applicants have reworded claim 4 to clarify it, which Applicants submit obviates the rejection.

Claim 6 calls for reinsertion of the lancet system into the housing. As just discussed, neither Levin nor Morita disclose a device in which the lancet system can even be removed from a housing, as recited in claim 1, much less reinserted, as called for in claim 6. Indeed, Morita and Levin both teach away from the reinsertable lancet system recited in claim 6.

Thus, the combination of Levin and Morita fails to teach the features recited in base claim 1, from which claims 3, 4 and 6 depend. Further, even if this were not so, there would be no motivation to combine these references as suggested by the Examiner. Applicants therefore respectfully request that the Examiner withdraw this rejection.

*b. Claim 7*

Claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Levin in view of Ruppert. The Examiner stated that Ruppert teaches a device which “[ensures] that a used needle does not re-enter the assembly . . . .” Office Action, pg. 6, ¶ 10. As alluded

above, it appears that the Examiner is reading the term “ejected” in Applicants’ original claim 7 on a lancing operation. The supposed “blocking mechanism” that the Examiner states is found in Rupport is indeed actuated during the lancing operation, and the removal of the lancet from the device actually releases this locking feature. Thus, the Examiner’s rejection only makes sense if the Examiner is interpreting the term “ejected” in originally presented claim 7 as reading on a lancing operation. Applicants did not intend this interpretation. In any event, to resolve the apparent misapprehension, amended claim 7 now calls for the blocking mechanism being actuated when the lancet system is *removed* from the housing. Since Rupport does not teach or suggest such a feature, Applicants request that the Examiner withdraw this rejection.

*c. Claim 9*

Claim 9 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Levin in view of U.S. Patent No. 5,423,847 to Strong et al. (“Strong”). As noted above, the base reference, Levin, does not disclose a lancet that can be removed from a housing of the lancing device, as claimed by Applicants, much less a lancet system whose needle cannot be reused after the lancet system has been removed. Strong does not cure the deficiency.

Strong teaches a lancet ejector 1 having a mouth 11 in which a lancet body 101 having a needle 103 can be inserted. The body 101 is integrally formed with an “isolating platform” 5. During lancing, the needle passes through hole 115 in plate 113 (Figs. 9 and 13) to puncture the skin. During ejection of the lancet after it is used, the fixation sleeve 117 of platform 5 “snaps” to a smaller diameter and the platform grips the lancet body 101. Strong, col. 15, lines 30-35. The lancet and the platform that is secured to it can then be discarded together.

The Examiner apparently relies on Strong for a blocking mechanism that is actuated *during a lancing operation*, as recited in Applicants’ dependent claim 9. As recited in Applicants’ claim 1, the blocking mechanism is actuated by an interaction *with the housing* such that after removal of the lancet system from the housing, the holding element of the housing is prevented from interacting with the holding element of the lancet system. No such interaction with a housing as claimed takes place during a lancing operation in the device disclosed by Strong, as claimed by Applicants. Instead, the “interaction” disclosed by Strong, if any, occurs when the platform 5 snaps onto and secures the lancet as the two of these elements are removed together from the ejector after a lancing operation. However, this interaction occurs with platform 5, not with a housing as claimed, and such interaction occurs only *after* the lancing operation, not *during* lancing as claimed.

Applicants agree with the Examiner that, after lancing, the ejector 1 of the Strong device cannot be reused on the same lancet due to the presence of an interlocking mechanism. However, Applicants do not claim such a feature. Indeed, in many embodiments incorporating Applicants' claims, *a lancet can be used multiple times before it is removed. See Applicants' specification, ¶ [0012].* "It should advantageously be possible to easily re-use a needle of a lancet system that has been inserted once." *Id.* This feature is now claimed in Applicants' new claims 31 and 32. The Examiner should appreciate that, while claim 9 calls for the blocking mechanism to be actuated during lancing, the effect of the blocking mechanism, namely, that the lancet system cannot be reused, need only occur after the lancet system is removed from the housing, as recited in claim 1. There is simply no hint of these inventive features that can be derived from Levin or Strong, alone or in combination. Applicants therefore request that this rejection be withdrawn.

*d. Claims 10 and 11*

Claims 10 and 11 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Levin in view of U.S. Patent No. 5,797,942 to Schraga ("Schraga"). According to the Examiner, "it would have been obvious to one of ordinary skill in the art . . . to enable the protective part of the needle to move during *ejection* in the device of Levin et al. to prevent accidental misuse or cross-contamination of needles." Office Action, pg. 7, ¶ 12 (italics added). As discussed above, the Examiner apparently is reading the term "ejection" appearing in Applicants' originally presented claim 10 on a needle tip that emerges from a lancing aid during lancing. Applicants have amended claim 10 to recite "*removal* of the lancet system from the lancing aid" to clarify what was intended. Applicants respectfully request that the Examiner withdraw this rejection.

The Examiner rejected claim 11 along with claim 10 without further commentary. Applicants thus do not know whether the Examiner in fact intended to reject claim 11. If the Examiner intended to reject claim 11 over the combination of Levin and Schraga, Applicant submits that Levin does not disclose a device whose needle can be removed as claimed in Applicants' claim 1, as discussed above. Indeed, Levin teaches away from such a feature. Additionally, Schraga does not teach a device in which the first position of the needle body is the same as the resting position, as recited in Applicants' claim 11. Instead, by comparing, e.g., Figs. 5A and 5B of Schraga, it appears that the resting position is positioned to the side of the position in which the lancet resides before lancing. Since Schraga does not disclose or suggest the features recited in claim 11, Applicants respectfully request that the Examiner withdraw this rejection.

*e. Claims 15, 18 and 19*

Claims 15, 18, and 19 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ruppert in view of U.S. Patent No. 6,783,537 to Kuhr et al. ("Kuhr"). As discussed above, Applicants have amended base claim 12 to recite that the protective portion of the needle body partially surrounds the needle tip when the lancet system is removed from the lancing aid. Ruppert does not disclose this claimed feature, as is also noted above, nor does Kuhr. Instead, Kuhr discloses a lancet magazine which mates with a lancing device, and in the process, a lancet is transferred to the lancing device while the protective cover for the tip of the lancet is pulled from the lancet blade and falls out of the lancet magazine. See Kuhr, col. 11, line 50 to col. 12, line 19. Thus, the lancet that is removed from the lancing aid after use with the device in Kuhr will have an exposed blade, unlike that claimed by Applicants. Since neither Ruppert nor Kuhr, alone or in combination, discloses all of Applicants' claim elements, this combination of references cannot render Applicants' claims obvious. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references).

Applicants cannot find a specific reason given in the Office Action for the rejection of claim 15. Nonetheless, in addition to the deficiencies just noted with regard to the base claim, Applicants see no disclosure in Ruppert or Kuhr of a blocking mechanism which is actuated independently of the protective portion of the needle body, as claimed by Applicants in claim 15.

As to claim 18, the Examiner states that the "the protective sheath [of Kuhr] has a predetermined breaking point so that the protective sheath may be cleanly removed from the needle." While this may be true, Applicants submit that it is not germane to the blocking mechanism recited in claim 12, nor does this disclosure appear to add anything to the protective sheath that is disclosed by Ruppert, which sheath also is removed and discarded before the lancet having an exposed needle is removed from the lancing device.

Finally, as to claim 19, the Examiner states that the "protective sheath (14) over the needle [in Kuhr] acts to enlarge the area of the needle." This statement is not understood. Applicants' claim 19 recites that actuation of the blocking mechanism enlarges at least one area of the needle body. The words "actuation of" were added to claim 19 to make clear that this is a functional recitation. In other words, the claim term "enlarge" is a verb, meaning that actuation of the blocking mechanism causes an area of the needle to become larger. No part of the lancet body disclosed in Kuhr becomes larger, much less as a result of actuation of a blocking mechanism as claimed by Applicants in claim 19.

The Examiner is respectfully requested to withdraw the rejection of claims 15, 18, and 19.

#### **NEW CLAIMS**

Applicants have added new claims 21-32. Applicants submit that these new claims are patentably distinguishable over the art cited by the Examiner and all art of record. Applicants respectfully request allowance of these new claims.

#### **CONCLUSION**

Applicants believe that the foregoing is a complete response to the outstanding Office Action and reconsideration is requested. Specifically, Applicants believe that all claims are now in condition for allowance and allowance thereof is earnestly solicited.

In the event Applicants have overlooked the need for a Petition for Extension of Time or payment of fee (except for Issue Fees), Applicants hereby petition therefor and authorize the United States Patent and Trademark Office to charge any additional fees for extension of time to Deposit Account No. 02-3223, Bose McKinney & Evans LLP.

If the Examiner has any questions regarding any of the foregoing, she is invited to telephone the undersigned at the telephone number listed below.

Respectfully submitted,

**BOSE McKINNEY & EVANS LLP**



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Michael C. Bartol  
Reg. No. 44,025

Bose McKinney & Evans LLP  
2700 First Indiana Plaza  
135 North Pennsylvania Street  
Indianapolis, Indiana 46204  
(317) 684-5281